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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,949

Examiner

Fozia M Hamud

Applicant(s)

SPRECHER ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 18-23 and 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Detailed Action

1. Receipt of Applicants' amendment filed on 12 June 2003 in Paper No.9, is acknowledged. Claims 1, 3-5, 16 and 17 have been amended. Claims 1-32 are pending.

Election/Restriction:

2. Applicant's election of the invention of Group I (claims 1-17 and 24), drawn to an isolated nucleic acid, an expression vector, a recombinant host cell and a method of producing the encoded protein, without traverse. Applicants also elect the nucleic acid encoding the polypeptide of SEQ ID NO:2, with traverse.

Applicants' ground of traversal is that SEQ ID Nos:2, 46, 18 and 22 recited in claims 1-17, 24 share a common structural feature of Zcytor17, because all of these sequences contain amino acid residues 20-225 of SEQ ID NO:2, which is considered to be the cytokine binding domain. Applicants, therefore, conclude that unity of invention exists and that it would be improper for the office to refuse to examine that which Applicants regard as their invention.

Applicants' grounds of traversal have been fully considered but are not deemed persuasive. The amino acid sequences of SEQ ID Nos: 2, 46, 18 and 22 are distinct inventions, because they are structurally distinct compounds. SEQ ID NO:2 consists of 732 amino acid residues, SEQ ID NO:46 consists of 649 amino acid residues, SEQ ID NO:18 consists of 324 amino acid residues and SEQ ID NO:22 consists of 239 amino acid residues. Applicants have not shown that having the amino acid residues 20-225 of SEQ ID NO:2, assures SEQ ID Nos: 2, 46, 18 and 22 to have the same biological

activity. Therefore, these sequences are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121, (see MPEP 2434). Absent evidence to the contrary, the nucleotide sequences encoding SEQ ID Nos:2, 46, 18 and 22 are presumed to represent independent and distinct inventions, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. Therefore, the isolated nucleic acid encoding the amino acid sequence set forth in SEQ ID NO:2 will be searched and examined. If a generic claim drawn to a nucleic acid encoding a polypeptide comprising residues 20-227 of SEQ ID NO:2 is found allowable, individual encompassed species may then be considered for rejoinder.

The requirement is still deemed proper and is therefore made FINAL.

Claims will be 1-17 and 24 will be searched and examined, in so far as they pertain to an isolated nucleic acid encoding the polypeptide of SEQ ID NO:2.

Claims 18-23, 25-32 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Specification:

3a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested "Nucleic Acid Encoding Cytokine Receptor ZCYTOR17".

3b. The Brief Description of the Drawings should be corrected. Figure 1 is shown in three panels (Figure 1A, Figure 1B and Figure 1C), however, the Brief Description of the Drawings only reflects one Figure 1. Appropriate correction of the Brief Description of the Drawings which reflects Figure 1A, Figure 1B and Figure 1C is required.

3c. The Brief Description of the Drawings describes a Figure 2, however, instant specification does not contain a Figure 2. Appropriate correction is required.

Information Disclosure Statement:

4a. None of the references cited on the PTO-1449 form submitted by Applicants on 06 June 2003 in Paper No: 7 have been considered, because the copies of the documents are missing. It is kindly requested that Applicants resubmit copies of the references with their response to this office action. All of the references will be considered once the copies are received. Applicants are thanked in advance for their cooperation and any inconvenience is regretted.

4b. US Application number 10/351,157, US Provisional Application Numbers 60/435,361, 60/389,108 and 60/350,325 have been considered per Applicants' request.

Claim objections:

5. Claim s 1-17 and 24 are objected to because of the following informalities:
Claims 1, 6, 12 and 14 are objected to, because they recite non-elected SEQ ID Nos.
Claims 3-5, 7-13, 15-17 and 24 are objected to in so far as they depend on claims 1, 6 or 14. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101/112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6a. Claims 1-17 and 24 of the instant invention are directed to an isolated nucleic acid encoding a polypeptide that comprises of amino acid residues 20-227, 20-51-, 20-543, 544-732, 20-732, and 1-732 of SEQ ID NO:2, a vector comprising said nucleic

acid, a recombinant host cell comprising said vector and a method of producing the encoded protein.

The specification describes the claimed nucleic acid as encoding a novel receptor and designates it "Zcytor17" (see page 2, lines 7-11). Instant specification states that the claimed nucleic acid encodes a protein having the structure of a class I cytokine receptor subfamily that includes gp130, LIF, IL-2, oncostatin M receptor and WSX-1 receptor, (see page 16, lines 3-9 and page 30, lines 17-25). The specification also states that the Zcytor17 has been shown to be up-regulated in monocyte cells and that it may be involved in regulating inflammation, asserting that it might be used as a marker for inflammation, (see page 60, lines 26-30). The specification also speculates that the Zcytor17 of the instant invention can be used to treat a subject that produces excess of either Zcytor17 ligand or Zcytor17 itself, (page 60, lines 16-25). Instant specification also asserts that the claimed nucleic acid can be used as probes to detect abnormalities or genotypes associated with chromosome 5q11, (page 90, lines 20-24).

However, beyond making the above assertions, instant specification does not disclose any information regarding physiologic or functional characteristics of the protein encoded by the claimed nucleic acid. Furthermore, the polypeptide encoded by the claimed nucleic acid has never been expressed, no biological activity was assayed or determined for it, its endogenous ligand is not identified and only a deduced amino acid sequence and general methods of expressing recombinant proteins is disclosed.

While, the instant specification asserts that the polypeptide encoded by the claimed nucleic acid can be used therapeutically, and discloses conventional protein

and nucleic acid administration techniques, it does not disclose specific diseases which can be treated or diagnosed using the claimed nucleic acid or the encoded polypeptide. Although instant specification asserts that the Zcytor17 of the instant invention might be involved in inflammation and that it is up-regulated in monocyte cells, it provides no data to support said allegation. Thus, the specification establishes no connection between any physiological condition and this protein, i.e, is the claimed nucleic acid or the encoded polypeptide over expressed, under expressed or completely lacking in any disorder? The specification provides no working examples as to the activity of the polypeptide encoded by the claimed nucleic acid, and one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein. Therefore, one of ordinary skill in the art would not be able to predict the activity or physiological importance of the polypeptide encoded by the claimed nucleic acid. The fact that the claimed nucleic acid sequence has been mapped to chromosome 5q11 region of chromosome 5 does not provide utility for the claimed nucleic acid, because, the role of the claimed nucleic acid or the encoded polypeptide in any disorder or disease is not disclosed by Applicants. The claimed nucleic acid can't be used to diagnose any disorder, because instant specification does not establish a link between the claimed nucleic acid and any disorder. For example, is there a reduction or over-production of said the claimed nucleic acid or the encoded polypeptide, relative to control tissues? No meaningful information will be obtained from tracking the level of expression of the claimed nucleotide or mapping the locus on a chromosome in which the claimed DNA is

located, because there is no physiological or biological significance attached to these nucleotides or the encoded proteins.

The claimed invention is directed to a nucleic acid of as yet undetermined function or biological significance, therefore, unless Applicants demonstrate the physiological significance or the biological role of the instant nucleic acid and the protein it encodes, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

5b. Claims 1-17 and 24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification does not define the physiological role of the Zcytor17 polypeptide encoded by the claimed nucleic acid, neither does it establish a link between the claimed nucleic acid or the encoded protein and a physiological condition. Therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded protein. The specification discloses only the sequence of the claimed nucleic acid and the encoded protein, and that is insufficient to establish a specific or substantial utility for the claimed invention.

Should Applicants establish an activity for the polypeptide of SEQ ID NO:2 encoded by the nucleic acid, instant specification would still fail to adequately describe and enable an isolated nucleic acid that encodes fragments 20-227, 20-519, 20-542 , 544-732 or 520-543, of the polypeptide of SEQ ID NO: 2. Applicants do not teach

which regions of the polypeptide of SEQ ID NO:2, are critical for the functional and structural integrity of the polypeptide. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a fragment of the polypeptide of SEQ ID NO:2, which retain the desired activity, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a nucleic acid or a polypeptide encoded thereby, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention, an isolated nucleic acid encoding the polypeptide that comprise fragments 20-227, 20-519, 20-542, 544-732 or 520-543 of SEQ ID NO: 2, that displays that desired activity, would be undue. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid

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which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

Conclusion:

6. No claim is allowed.


Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
14 August 2003


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